

— For changing RMS
I'M AT MY BEST WHEN MY

MIND + **BODY**
ARE IN BALANCE

Not actual patients.

What is MAYZENT® (siponimod) tablets?

MAYZENT is a prescription medicine that is used to treat relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

It is not known if MAYZENT is safe and effective in children.

IMPORTANT SAFETY INFORMATION

Do not take MAYZENT if you:

- have a CYP2C9*3/*3 genotype. Before starting treatment with MAYZENT, your CYP2C9 genotype should be determined by your health care provider. Ask your health care provider if you are not sure.
- have had a heart attack, chest pain called unstable angina, stroke or mini-stroke (transient ischemic attack or TIA), or certain types of heart failure in the last 6 months
- have certain types of heart block or irregular or abnormal heartbeat (arrhythmia), unless you have a pacemaker

RMS=relapsing multiple sclerosis.

Please see additional Important Safety Information throughout this brochure and click [here](#) for full Prescribing Information, including Medication Guide.

ONCE-DAILY
MAYZENT®
(siponimod) 1 mg • 2 mg
tablets

**FOR YOUR CHANGING
RMS, STAY AHEAD OF
DISABILITY PROGRESSION**

*The first and only pill studied
and proven to delay disability
progression in people
with more progressed RMS.*



HOW RMS CHANGES



**HOW MAYZENT SLOWS
DISABILITY PROGRESSION**



HOW MAYZENT WORKS



OTHER STUDY RESULTS



**ALONGSIDE™ MAYZENT
& FINANCIAL SUPPORT**



GLOSSARY





RECOGNIZING CHANGING RMS

RMS can change over time, affecting both the mind and body. These changes can be gradual and subtle, so it's important to **tell your doctor if anything feels different.**

Disability progression is commonly measured by the **Expanded Disability Status Scale (EDSS)**. Your EDSS score is determined by how you function in the 8 key areas below and can range from 0 to 10. The higher your EDSS score, the greater your level of disability.



Assistance
required to
walk



Trouble with
memory or
concentration
(brain fog)



Problems with
coordination



Bowel and
bladder
issues



Weakness or
problems
moving limbs
(MS fatigue)



Vision
problems



Difficulty with
speech or
swallowing



Numbness
or loss of
sensation

Experiencing any changes? Talk with your doctor about anything you're noticing. The MAYZENT[®] Discussion Guide can help! Find it at mayzent.com/guide.

IMPORTANT SAFETY INFORMATION (cont)

MAYZENT may cause serious side effects, including:

- 1. Slow heart rate (bradycardia or bradyarrhythmia) when you start taking MAYZENT.** MAYZENT can cause your heart rate to slow down, especially after you take your first dose. You should have a test to check the electrical activity of your heart called an electrocardiogram (ECG) before you take your first dose of MAYZENT.

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WHAT CAUSES RMS TO CHANGE

RMS is caused by your immune system mistakenly attacking the protective coating (myelin) surrounding nerves in the central nervous system (CNS). The impact of these attacks can change over time:

- Initially, the attacks cause inflammation that can lead to relapses
- Although there may be fewer relapses over time, this inflammation can lead to nerve damage in the brain and spinal cord (neurodegeneration)

This can cause changes in RMS and bring new or worsening symptoms that may lead to permanent disability.

See *How MAYZENT® Works* on the next page.

Learn more in the “Understanding How RMS Changes Over Time” video at [SpotlightOnMayzent.com](https://www.spotlightonmayzent.com).



“I’ve noticed that MAYZENT helps to delay my disability progression and that gives me hope.”

— **BECKY E.**, MAYZENT Patient

IMPORTANT SAFETY INFORMATION (cont)

MAYZENT may cause serious side effects, including (cont):

1. Slow heart rate (bradycardia or bradyarrhythmia) when you start taking MAYZENT (cont).

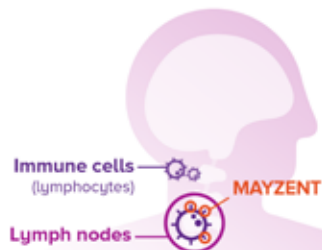
During the initial up dosing period (4 days for the 1-mg daily dose or 5 days for the 2-mg daily dose), if you miss 1 or more doses of MAYZENT, you need to restart the up dosing. Call your health care provider if you miss a dose of MAYZENT.

Please see additional Important Safety Information throughout this brochure and click [here](#) for full Prescribing Information, including Medication Guide.



HOW MAYZENT[®] WORKS

TRAPPING LYMPHOCYTES



It's believed that MAYZENT works by binding with two key receptors on lymphocytes, trapping them in the lymph nodes in order to **minimize damage to the nerves**.

ENTERS THE CNS



MAYZENT also readily enters the CNS (brain and spinal cord) to **possibly have an effect where RMS is active** and where nerve damage (neurodegeneration) is known to occur.*

*This effect was only observed in animal studies.



Because of the way the body processes MAYZENT, most people's immune cell count will **return to their normal range within 10 days** after stopping treatment. For some people, MAYZENT may continue to lower immune cell count for up to 3-4 weeks after the last dose.

While the exact way in which MAYZENT works on MS is unknown, it's believed to involve a reduction of immune cells called lymphocytes in the brain and spinal cord.

IMPORTANT SAFETY INFORMATION (cont)

MAYZENT may cause serious side effects, including (cont):

2. Infections. MAYZENT can increase your risk of serious infections that can be life-threatening and cause death. MAYZENT lowers the number of white blood cells (lymphocytes) in your blood. This will usually go back to normal within 3 to 4 weeks of stopping treatment. Your health care provider should review a recent blood test of your white blood cells before you start taking MAYZENT.



Learn more in "The Science Behind How MAYZENT Works" video at [SpotlightOnMayzent.com](https://www.spotlightonmayzent.com).

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STAY AHEAD OF PROGRESSION WITH MAYZENT[®]

The first and only pill studied and proven to delay disability progression in people with more progressed RMS*

In the largest clinical study of people with progressing RMS, MAYZENT was proven to help stay ahead of disability progression.

Overall clinical study results for 3-month confirmed disability progression were:

NEARLY
3 out of 4



**SHOWED NO CONFIRMED
DISABILITY PROGRESSION (CDP)[†]**

[†]Nearly 3 out of 4 is 74%, compared to 68% taking placebo.

21%



**LOWER CHANCE OF OVERALL
DISABILITY PROGRESSION[‡]**

[‡]Compared to those taking placebo.

The effect of MAYZENT was significant in people who had a relapse in the 2 years before the clinical study, but not considered significant in people who had not.

Disability progression was measured by assessing changes in the EDSS. Any change that remained consistent for at least 3 months was considered CDP.[§]

SPOTLIGHT ON
MAYZENT[™]
VIDEO SERIES



Learn more in “The Effectiveness of MAYZENT” video at **SpotlightOnMayzent.com**.

IMPORTANT SAFETY INFORMATION (cont)

MAYZENT may cause serious side effects, including (cont):

2. Infections (cont). Call your health care provider right away if you have any of these symptoms of an infection during treatment with MAYZENT and for 3 to 4 weeks after your last dose of MAYZENT:

- fever
- tiredness
- body aches
- chills
- nausea
- vomiting
- headache with fever, neck stiffness, sensitivity to light, nausea, confusion (these may be symptoms of meningitis, an infection of the lining around your brain and spine, and/or encephalitis, an infection of the brain)

*People in *EXPAND* had a mean EDSS score of 5.4.

§CDP is not the only way to measure disability progression.

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ADDITIONAL RESULTS FROM THE MAYZENT[®] CLINICAL STUDY



No significant difference between MAYZENT and placebo in a timed 25-foot walk test

The timed 25-foot walk test measures how quickly someone can walk 25 feet. The score is the average of two of these tests.

Because there was no significant difference in the walk test results, it can't be determined by this clinical study whether the results below were due to treatment with MAYZENT or if they happened by chance.

55% 

**REDUCTION IN ANNUAL
RELAPSE RATE (ARR)***
in people on MAYZENT
vs placebo

*ARR is the average number
of relapses someone has
in 1 year.

81% 

**REDUCTION IN NEW OR
ENLARGING T2 LESIONS. The
mean[†] number of lesions was
0.70 for people on MAYZENT
vs 3.60 for placebo**

[†]The mean is the average number
of new or enlarging T2 lesions
experienced over all visits.

23% 

**REDUCTION IN BRAIN VOLUME LOSS (BVL)
in people on MAYZENT vs placebo**

Brains typically lose volume as all people age.
But in people with MS, tissue damage from
inflammation and nerve damage can increase
the rate at which people lose brain volume.[‡]

[‡]The change for those taking MAYZENT was 0.50%
and 0.65% for those taking placebo.

IMPORTANT SAFETY INFORMATION (cont)

MAYZENT may cause serious side effects, including (cont):

3. Progressive multifocal leukoencephalopathy (PML). MAYZENT can increase your risk for PML, which is a rare brain infection that usually leads to death or severe disability. If PML happens, it usually happens in people with weakened immune systems but has happened in people who do not have weakened immune systems. Symptoms of PML get worse over days to weeks. Call your doctor right away if you

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SUPPORT THAT HELPS YOU START AND STAY ON TREATMENT

Things can be simpler when you're prepared. **Alongside™ MAYZENT®** helps prepare you for your MAYZENT experience. You'll connect with a dedicated Alongside MAYZENT Coordinator who will be there for you as you begin treatment. You can count on your Coordinator for one-on-one help with:



2 onboarding steps
to get started



Financial support
options built around
your needs



Navigating insurance
coverage and options
available to you

Be ready for what comes next with Alongside MAYZENT.

Learn more about how your Alongside MAYZENT Coordinator can help at mayzent.com/alongside.



"I can reach out to an Alongside Coordinator whenever I need support. They keep me on track with my once-daily MAYZENT."

— **MITCH W.**, MAYZENT Patient

IMPORTANT SAFETY INFORMATION (cont)

MAYZENT may cause serious side effects, including (cont):

- 3. (cont).** have any new or worsening neurologic symptoms that have lasted several days, including:
- weakness on 1 side of your body
 - loss of coordination in your arms and legs
 - decreased strength
 - problems with balance
 - changes in your vision
 - changes in your thinking or memory
 - confusion
 - changes in your personality

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SUPPORT WHILE NAVIGATING FINANCES

Sometimes navigating insurance and paying for treatment can be a challenge. Your Alongside™ MAYZENT® Coordinator will work with you to check your coverage and see if you qualify for any savings options.

Nearly 90% of patients with commercial and government health insurance get approved for MAYZENT.*



The MAYZENT Access Card PAY AS LITTLE AS \$0[†]

for MAYZENT if you're eligible

Learn more about how you may be able to
save on MAYZENT at [mayzent.com/save](https://www.mayzent.com/save).



Financial support for pretests

Novartis offers options to help cover or reduce costs of various tests (subject to eligibility requirements)[‡]



The Bridge Program

You may be eligible to receive up to 12 months of medication for free[§] while insurance coverage is being approved



Free medication for people in need

The Novartis Patient Assistance Foundation (NPAF), an independent charitable organization, can provide medication to those who are experiencing financial hardship and have limited or no prescription coverage

*As of July 2021.

[†]Limitations apply. Up to an \$18,000 annual limit. Offer not valid under Medicare, Medicaid, or any other federal or state program. Novartis reserves the right to rescind, revoke, or amend this Program without notice. See complete Terms & Conditions for details at www.mayzent.com.

[‡]Limitations apply. Valid only for those with private insurance. The Program includes Medical reimbursement up to \$900, after a \$125 deductible is paid by the patient. Medical co-pay support offer is for covered initial assessments/examinations and first-dose observations (FDOs) provided without regard to whether the patient continues on with MAYZENT therapy. Patients are required to report any benefits they receive under the MAYZENT Medical Co-Pay Program to their insurance company. This offer is not valid for prescriptions or medical assessments for which payment may be made in whole or in part under a federal or state health care program, including but not limited to Medicare or Medicaid, or for residents of RI. Novartis reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

[§]Eligible patients must have commercial insurance and a valid prescription for MAYZENT. By participating, patient acknowledges intent to pursue insurance coverage for MAYZENT with their health care provider. Program requires the submission of a request for coverage within 9 months post-Program initiation in order to remain eligible. Patients will receive their maintenance drug supply each month for up to 12 months or until they receive insurance coverage approval, whichever occurs earlier. Program is not available to patients who are uninsured or whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, or any other federal or state program, or where prohibited by law. Patients may be asked to re-verify insurance coverage status during the course of the Program. No purchase necessary. Program is not health insurance, nor is participation a guarantee of insurance coverage. Other limitations may apply. Novartis reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.



DEFINITIONS OF TERMS USED IN THIS BROCHURE

Types of multiple sclerosis (MS)

Active secondary progressive multiple sclerosis (active SPMS):

the early stage of SPMS in which people experience fewer relapses but don't bounce back as well between relapses and have increased disability. Active SPMS means a person may have had at least 1 relapse in the last 2 years.

Clinically isolated syndrome (CIS): when you experience MS-like symptoms caused by inflammation and damage to myelin, but a definite diagnosis of MS cannot yet be made.

Relapsing multiple sclerosis (RMS): a general term used for all forms of MS that have distinct episodes of relapses, including CIS, RRMS, and active SPMS.

Relapsing-remitting multiple sclerosis (RRMS): the most common type of MS, characterized by episodes during which symptoms get worse (relapses) but are then followed by periods of recovery (remissions). About 85% of people with MS are first diagnosed with RRMS.

Secondary progressive multiple sclerosis (SPMS): an advanced stage of MS that follows RRMS, in which symptoms and disability often get worse with or without relapses.

Some other terms associated with MS

Central nervous system (CNS): the system in your body made up of the brain, spinal cord, and optic nerve.

Clinical study: a controlled study environment to document and understand if a drug is effective and evaluate its safety and side effects.

Confirmed disability progression (CDP): any change in disability that remains consistent over a certain period of time.

Disability progression: lingering or worsening of symptoms between relapses that, over time, leads to increased cognitive and physical disability.

Expanded Disability Status Scale (EDSS): the EDSS is a method of measuring disability progression and monitoring changes in the level of disability over time. It is widely used in clinical studies and in the assessment of people living with multiple sclerosis (MS).

Inflammation: part of your body's immune response to help protect from infection. In certain conditions, such as MS, your immune system attacks your body's own tissue by mistake and the resulting inflammation causes damage.

Your doctor is always the best source of information about MS.



DEFINITIONS OF TERMS USED IN THIS BROCHURE

Some other terms associated with MS (cont)

Lymphocytes: a type of white blood cell that plays several roles in the immune system, including protection against bacteria, viruses, fungi, and parasites. In people living with MS, lymphocytes mistakenly attack the CNS.

Myelin: the protective layer around nerve fibers in the CNS.

Neurodegeneration: damage in the brain and spinal cord.

Permanent disability: irreversible cognitive and physical symptoms.

Placebo: a baseline inactive treatment given to one group in clinical trials to help researchers understand the efficacy of a new medical treatment.

Progression: the shift from less inflammation and relapses to increased nerve damage. This can lead to worsening cognitive and physical symptoms that accumulate over time.

Relapse: also called a “flare-up” or “exacerbation,” an episode in which MS symptoms get worse, or new ones arise, for a period of 1 day to several months, followed by at least 30 days of stability.

Titration: a slow increase of the dose of your medication to help your body adjust.

T2 lesions: T2 lesions, also called plaques, can be detected on MRI scans to measure disease activity in multiple sclerosis (MS).

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ONCE-DAILY
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—JARKESHIA M., MAYZENT[®] Patient

LEARN MORE AT [MAYZENT.COM](https://www.mayzent.com)



Find helpful resources
and downloads [here](#)



Watch the **Spotlight**
on **MAYZENT** video
series [here](#)



“I know what my limits are, and I’m happy with what I can keep doing.
I feel like MAYZENT has helped to slow down my disability progression.”

— **LAUREN B.**, MAYZENT Patient

IMPORTANT SAFETY INFORMATION (cont)

MAYZENT may cause serious side effects, including (cont):

4. A problem with your vision called macular edema. Macular edema can cause some of the same vision symptoms as a multiple sclerosis (MS) attack (optic neuritis). You may not notice any symptoms with macular edema. If macular edema happens, it usually starts in the first 1 to 4 months after you start taking MAYZENT.

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- have a CYP2C9*3/*3 genotype. Before starting treatment with MAYZENT, your CYP2C9 genotype should be determined by your health care provider. Ask your health care provider if you are not sure.
- have had a heart attack, chest pain called unstable angina, stroke or mini-stroke (transient ischemic attack or TIA), or certain types of heart failure in the last 6 months
- have certain types of heart block or irregular or abnormal heartbeat (arrhythmia), unless you have a pacemaker

MAYZENT may cause serious side effects, including:

- 1. Slow heart rate (bradycardia or bradyarrhythmia) when you start taking MAYZENT.** MAYZENT can cause your heart rate to slow down, especially after you take your first dose. You should have a test to check the electrical activity of your heart called an electrocardiogram (ECG) before you take your first dose of MAYZENT.

During the initial updosing period (4 days for the 1-mg daily dose or 5 days for the 2-mg daily dose), if you miss 1 or more doses of MAYZENT, you need to restart the updosing. Call your health care provider if you miss a dose of MAYZENT.

- 2. Infections.** MAYZENT can increase your risk of serious infections that can be life-threatening and cause death. MAYZENT lowers the number of white blood cells (lymphocytes) in your blood. This will usually go back to normal within 3 to 4 weeks of stopping treatment. Your health care provider should review a recent blood test of your white blood cells before you start taking MAYZENT.

Call your health care provider right away if you have any of these symptoms of an infection during treatment with MAYZENT and for 3 to 4 weeks after your last dose of MAYZENT:

- fever
- tiredness
- body aches
- chills
- nausea
- vomiting
- headache with fever, neck stiffness, sensitivity to light, nausea, confusion (these may be symptoms of meningitis, an infection of the lining around your brain and spine, and/or encephalitis, an infection of the brain)

- 3. Progressive multifocal leukoencephalopathy (PML).** MAYZENT can increase your risk for PML, which is a rare brain infection that usually leads to death or severe disability. If PML happens, it usually happens in people with weakened immune systems but has happened in people who do not have weakened immune systems. Symptoms of PML get worse over days to weeks. Call your doctor right away if you have any new or worsening neurologic symptoms that have lasted several days, including:

- weakness on 1 side of your body
- loss of coordination in your arms and legs
- decreased strength
- problems with balance
- changes in your vision
- changes in your thinking or memory
- confusion
- changes in your personality

- 4. A problem with your vision called macular edema.** Macular edema can cause some of the same vision symptoms as a multiple sclerosis (MS) attack (optic neuritis). You may not notice any symptoms with macular edema. If macular edema happens, it usually starts in the first 1 to 4 months after you start taking MAYZENT. Your health care provider should test your vision before you start taking MAYZENT and any time you notice vision changes during treatment with MAYZENT. Your risk of macular edema is higher if you have diabetes or have had an inflammation of your eye called uveitis.

Call your health care provider right away if you have any of the following: blurriness or shadows in the center of your vision, a blind spot in the center of your vision, sensitivity to light, or unusually colored (tinted) vision.

Before taking MAYZENT, tell your health care provider about all of your medical conditions, including if you:

- have an irregular or abnormal heartbeat
- have a history of stroke or other diseases related to blood vessels in the brain
- have breathing problems, including during your sleep
- have a fever or infection, or you are unable to fight infections due to a disease or are taking medicines that lower your immune system. Tell your health care provider if you have had chickenpox or have received the vaccine for chickenpox. Your health care provider may do a blood test for chickenpox virus. You may need to get the full course of vaccine for chickenpox and then wait 1 month before you start taking MAYZENT.
- have slow heart rate
- have liver problems
- have diabetes
- have eye problems, especially an inflammation of the eye called uveitis
- had or now have a type of skin cancer called basal cell carcinoma (BCC), melanoma, or squamous cell carcinoma (SCC)
- have high blood pressure

IMPORTANT SAFETY INFORMATION (cont)

- are pregnant or plan to become pregnant. MAYZENT may harm your unborn baby. Talk to your health care provider right away if you become pregnant while taking MAYZENT or if you become pregnant within 10 days after you stop taking MAYZENT.
 - If you are a woman who can become pregnant, you should use effective birth control during your treatment with MAYZENT and for at least 10 days after you stop taking MAYZENT.
 - **Pregnancy Registry:** There is a registry for women who become pregnant during treatment with MAYZENT. If you become pregnant while taking MAYZENT, talk to your health care provider. For more information or to register, contact MotherToBaby by calling 1-877-311- 8972, by sending an email to MotherToBaby@health.ucsd.edu, or go to www.mothertobaby.org/join-study.
- are breastfeeding or plan to breastfeed. It is not known if MAYZENT passes into your breast milk. Talk to your health care provider about the best way to feed your baby if you take MAYZENT.

Tell your health care provider about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements. Especially tell your health care provider if you take medicines to control your heart rhythm (anti-arrhythmics), or blood pressure (antihypertensives), or heart beat (such as calcium channel blockers or beta-blockers); take medicines that affect your immune system, such as beta-interferon or glatiramer acetate, or any of these medicines that you took in the past.

Tell your health care provider if you have recently received a live vaccine. You should avoid receiving **live** vaccines during treatment with MAYZENT. MAYZENT should be stopped 1 week before and for 4 weeks after receiving a live vaccine. If you receive a live vaccine, you may get the infection the vaccine was meant to prevent. Vaccines may not work as well when given during treatment with MAYZENT.

MAYZENT may cause possible side effects, including:

- **increased blood pressure.** Your health care provider should check your blood pressure during treatment with MAYZENT.

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- **liver problems.** MAYZENT may cause liver problems. Your health care provider should do blood tests to check your liver before you start taking MAYZENT. Call your health care provider right away if you have any of the following symptoms of liver problems:
 - nausea
 - vomiting
 - stomach pain
 - tiredness
 - loss of appetite
 - your skin or the whites of your eyes turn yellow
 - dark urine
- **breathing problems.** Some people who take MAYZENT have shortness of breath. Call your health care provider right away if you have new or worsening breathing problems.
- **swelling and narrowing of the blood vessels in your brain.** A condition called PRES (Posterior Reversible Encephalopathy Syndrome) has happened with drugs in the same class. Symptoms of PRES usually get better when you stop taking MAYZENT. However, if left untreated, it may lead to a stroke. Call your health care provider right away if you have any of the following symptoms: sudden severe headache, sudden confusion, sudden loss of vision or other changes in vision, or seizure.
- **severe worsening of multiple sclerosis after stopping MAYZENT.** When MAYZENT is stopped, symptoms of MS may return and become worse compared to before or during treatment. Always talk to your doctor before you stop taking MAYZENT for any reason. Tell your health care provider if you have worsening symptoms of MS after stopping MAYZENT.
- **a type of skin cancer called basal cell carcinoma (BCC), melanoma, and squamous cell carcinoma (SCC).** Tell your doctor if you have any changes in the appearance of your skin, including changes in a mole, a new darkened area on your skin, a sore that does not heal, or growths on your skin, such as a bump that may be shiny, pearly white, skin-colored, or pink. Your doctor should check your skin for any changes at the start of and during treatment with MAYZENT. Limit the amount of time you spend in sunlight and ultraviolet (UV) light. Wear protective clothing and use a sunscreen with a high sun protection factor.

The most common side effects of MAYZENT include: headache, high blood pressure (hypertension), and abnormal liver tests.

These are not all of the possible side effects of MAYZENT. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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